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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information from Organizations Utilizing Business Models Supporting Private

Sector Vaccine Management

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, National Vaccine Program Office.

ACTION: Notice.

SUMMARY: This is a Request for Information (RFI) about business models, existing, under development or planned, that support health care providers for any of the components related to private-sector immunization services (e.g., excluding vaccines provided through federal and state programs, such as the Vaccines for Children Program, Children's Health Insurance Program, Medicaid, and Medicare): vaccine purchase, distribution, storage and handling, inventory management, reporting to Immunization Information Systems (IIS), including models for populating IIS directly/automatically from electronic health records (EHRs), immunization coverage assessment, forecasting vaccine demand, and billing. The RFI is being issued by the National Vaccine Program Office (NVPO) of the U.S. Department of Health and Human Services.

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The NVPO is located in the Office of the Assistant Secretary for Health (ASH), Office of the Secretary (OS), U.S. Department of Health and Human Services (HHS). The NVPO is responsible for coordinating and ensuring collaboration among the many federal agencies involved in vaccine and immunization activities.

The National Vaccine Program was established in compliance with Title XXI of the Public Health Service Act (P.L. 99-660) (§2101) (42 U.S. Code 300aa-et seq (PDF - 78 KB)) to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. Development of a National Vaccine Plan (NVP) has been mandated to the NVPO as a mechanism for the Director of the National Vaccine Program (the Assistant Secretary for Health) to communicate priorities for both federal and nonfederal stakeholders regarding vaccine research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines in order to carry out the program's responsibilities. Goal 4 of the plan, Ensure a Stable Supply of, Access to, and Better Use of Recommended Vaccines in the United States, focuses in part on increasing and improving access to vaccines in health care provider settings. This RFI seeks information on innovative business models to support health care providers to increase and improve their ability to provide immunization services, as described below.

In its efforts to promote vaccination coverage across the lifespan, the NVPO is seeking information about business models, existing, under development or planned, that enable health care providers to offer vaccines to their privately-insured/private-pay patients. The NVPO is most interested in innovative business models aimed at reducing any of the barriers to

implementing vaccination services such as vaccine purchase, billing, storage and handling, IIS reporting, including models for populating IIS directly/automatically from EHRs, forecasting vaccine demand, and managing private vaccine inventories. In addition, the NVPO is interested in models that can demonstrate improvements in the immunization coverage rates of the patients seen in the health care settings utilizing such models as well as improvements in reporting to IIS.

DATES: Information from Organizations Utilizing Business Models Supporting Private Sector Vaccine Management responsive to this RFI should be submitted as described in the ADDRESSES section below no later than midnight, 12:00 am EDT on [INSERT DATE 15]. **DAYS FOLLOWING DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Information from Organizations Utilizing Business Models Supporting Private Sector Vaccine Management responsive to this RFI should be submitted in Portable Document Format (PDF) only and be submitted via email to nvpo@hhs.gov. The name(s) of all PDF files uploaded should begin with "NVPO_RFI_MODEL" followed by the organization name and the sequential number of the file, if more than one file is submitted. All submissions responsive to this RFI must be made as indicated above. Mailed paper submissions will not be reviewed.

FOR FURTHER INFORMATION CONTACT: National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services; telephone (202) 690-5566; email: nvpo@hhs.gov.

SUPPLEMENTARY INFORMATION:

Responses to this RFI should include the organization's full name and headquarters location.

They should also include the name of a point-of-contact and his/her e-mail and conventional mailing addresses. Companies are invited to respond to the following request for information:

- 1. Description of the business model, existing, under development or planned, and how it addresses any of the following:
 - a. Purchase of vaccines for privately-insured/private pay patients
 - b. Bill private insurers for vaccines and vaccine administration
 - c. Proper storage and handling of privately-purchased vaccines
 - d. Management of private vaccine inventories separate from public vaccine inventories
 - e. Report vaccine administration to IIS, including models for populating IIS directly/automatically from EHRs
 - f. Forecast vaccine demand
 - g. Quality improvement efforts to improve vaccination coverage
 - h. Ability to conduct mass vaccination clinics as part of an emergency response
 - Implementation of vaccination as part of occupational health clinics (including federally-sponsored occupational health clinics).
- 2. Description of the practices served, or planned to be served, including geographic locations, patients served (e.g., pediatrics, specialists, health care providers serving

adults, etc.), and practice types (e.g., large health system, private practices, group practices, etc.).

3. Summary of any evaluations of the business model's effectiveness in expanding accessibility to vaccines for privately-insured patients to new groups of health care providers who did not previously provide immunizations or to existing health care providers to expand their immunization services and/or improvements in vaccination coverage for patients served by participating practices.

This request for information is for informational purposes only and shall not be construed as a solicitation for funding applications/proposals or as creating an obligation on the part of the government. The government will not pay for the preparation costs of any information submitted in response to this RFI. Responses to any of the above areas are welcome; respondents should not feel compelled to address all the issues identified in the request. Responses will be compiled without company identifiers and shared with HHS Operating Divisions (e.g., the Centers for Disease Control and Prevention) and advisory committees as appropriate. Public release of the data submitted is governed by the Freedom of Information Act (https://www.hhs.gov/foia/). Response to the RFI will not be returned.

Information collection sponsored by the NVPO required for the purposes of informing the National Vaccine Program and the National Vaccine Plan is not subject to Chapter 35 of title 44, United States Code [the Paperwork Reduction Act] as indicated in 42 U.S.C. 300aa-1 note (section 321 of Public Law 99-660).

DATED: January 4, 2017.

Roula K. Sweis

Chief of Operations and Management

National Vaccine Program Office

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